PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

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PCT

WRITTEN OPINION OF THE INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

(PCT Rule 66)

Date of mailing *(day/month/year)*	29.06.2005
Applicant's or agent's file reference 041748wo HPJ	**REPLY DUE** **within 2 month(s)** from the above date of mailing

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP2004/007215	02.07.2004	03.07.2003

International Patent Classification (IPC) or both national classification and IPC
B32B27/08, B32B27/30, B32B27/32, B32B27/36, A61J1/00

Applicant
B. BRAUN MEDICAL AG et al.

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1. ☒ The written opinion established by the International Searching Authority:
   ☐ is ☒ is not
   considered to be a written opinion of the International Preliminary Examining Authority

2. This first report contains indications relating to the following items:
   - ☒ Box No. I Basis of the opinion
   - ☐ Box No. II Priority
   - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - ☐ Box No. IV Lack of unity of invention
   - ☒ Box No. V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - ☐ Box No. VI Certain documents cited
   - ☐ Box No. VII Certain defects in the international application
   - ☒ Box No. VIII Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

   When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(e).
   How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.
   Also: For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4*bis*. For an informal communication with the examiner, see Rule 66.6. For an additional opportunity to submit amendments, see Rule 66.4.

   If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary report on patentability (Chapter II of the PCT) must be established according to Rule 69.2 is: 03.11.2005

Name and mailing address of the international preliminary examining authority:	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Seiberlich, P Telephone No. +49 89 2399-8663

WRITTEN OPINION OF THE INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

International application No.
PCT/EP2004/007215

10/562368

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this opinion is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed")*:

Description, Pages	
1-20	as originally filed
Claims, Numbers	
1-15	received on 04.05.2005 with letter of 03.05.2005
Drawings, Sheets	
1/4-4/4	as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

WRITTEN OPINION OF THE INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

International application No.
PCT/EP2004/007215

Box No. V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-15
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-15
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-15
	No:	Claims	

2. Citations and explanations:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

The following document/s (D) is/are referred to in this communication:

D1: EP-A-0 774 348 (BRAUN MELSUNGEN AG)

1. Novelty

1.1 Document D1, which is considered to represent the most relevant state of the art, discloses sterilisable co-extruded films for wrapping containers for solutions, suspensions, solids or mixtures for parenteral, enteral or stomach tube feeding.
The tube consists of three layers, i.e.
(a) polypropylene homopolymer (homo-PP, outer layer),
(b) ethylene vinylalcohol copolymer (EVOH), in particular a copolymer with an ethylene content of 27-38 mole% and
(c) a single-phase PP homo- or co-polymer (inner layer).
The three layers (a), (b) and (c) have thicknesses of 20-40 μm (a), 15-35 μm (b) and 30-50 μm, respectively; cf. D1, the passages cited in the Search Report, in particular the claims.
The material of inner layer (b) is selected to provide the required oxygen barrier properties. It is clear that the ethylene content of the EVOH copolymer is selected to maintain barrier properties during sterilization at 121 °C (cf. p 2/3, bridging paragraph and p 3/l 11-21 and 37).

1.2 The wording of present claim 1 is not clear, since it does not define the matter for which protection is sought (see hereinafter under item VIII).
It appears from the present application that the EVOH material of the intermediate layer of the claimed films corresponds to the material used in D1 (cf. present claim 5). Since the material of the intermediate layer determines the oxygen transmission rate through the film, it is to be assumed that the films according to D1 and the films of the present application have the same properties as regards oxygen transmission rates.
The films according to present claim 1 allow for desorption of water absorbed in the intermediate layer during sterilization, whereas document D1 is silent as regards such

desorption properties.

The claimed films differ from those according to D1 in the nature of the outer layer (i.e. the presence of a (co)PET outer layer. Thus, the claimed films are novel over the disclosure in D1. The subject-matter of present claims 1-15 therefore appears to meet the requirements of Article 33(2) PCT.

2. Inventive Step

The claimed films differ from the most relevant state of the art (D1) in the nature of their outer layer and in their desorption properties (see hereinabove under 1.2).
The problem to be solved by the present application may therefore be regarded as to provide multilayer films having a low oxygen transmission rate (i.e. <0.7 ml/m^{2}d) and at the same time allowing for improved recovery of the gas barrier properties of the core layer after sterilization.
It appears from a comparison of the results presented in Fig. 3 that the presence of an outer layer of PET instead of PP renders the obtainable films more effective in the desorption of water and, thus, improves the long term barrier properties of the corresponding container.
None of the documents of the prior art contains an incentive for the skilled person to combine layers of a saponified polyolefin-vinyl acetate copolymer in combination with layers of a polyalkylene terephthalate resin (e.g. bonded by means of an adhesive) when aiming at structures allowing for improved desorption of water e.g. absorbed during sterilization. Thus, the subject-matter of present claims 1, 12 and 13 appears to meet the requirements of Article 33(3) PCT.

Claims 2-11, 14 and 15 are dependent on claim 1 or 13 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

Re Item VIII
Certain observations on the international application

The claims do not meet the requirements of Article 6 PCT in that the matter for which

protection is sought is not defined.

Claim 1 attempts to define the subject-matter in terms of the result to be achieved, namely the ability to desorb water absorbed in the intermediate layer, which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result. Moreover, neither the claims nor the description appear to specify details concerning a method to determine the ability to desorb water absorbed in the intermediate layer. Thus, the claim is also not clear as regards the definition of the property as such.